



## Complications of Pediatric Cardiac Catheterization: A 3-Year Study

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To determine the current risk of pediatric cardiac catheterization, the complications and incidents of all catheterizations performed in a pediatric laboratory between January 1986 and October 1988 were prospectively recorded and compared with results from a 1974 study from the same institution. In the current study 1,037 catheterizations, 885 diagnostic and 152 diagnostic/interventional procedures, were performed in 888 patients (aged 1 day to 27 years, median 15.6 months). There were 15 major complications (1.4%), 70 minor complications (6.8%) and 39 incidents (3.9%). Two patients died as a result of the procedure and two as a result of pericatheterization clinical deterioration caused by the cardiac abnormality.

The great majority of complications were successfully treated or were self-limited and the patients had no residua. Of patients with 13

nonfatal major complications and 70 minor complications, residua were evident in 7 patients and 3 without evident residua had the potential for sequelae (0.7% and 0.3% of catheterizations).

A comparison of the diagnostic and balloon atrial septostomy cases in the present study with similar cases in the 1974 study shows that the incidence of major complications has decreased from 2.9% to 0.9% ( $p < 0.0001$ ); minor complications and incidents have decreased from 11.7% to 7.9% ( $p < 0.006$ ) and pericatheterization deaths not attributable to catheterization have decreased from 2.8% to 0.2% ( $p < 0.0001$ ). Changes in pericatheterization medical management, patient selection for catheterization and catheterization techniques probably account for these improvements.

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Despite advances in the noninvasive evaluation of patients with congenital heart disease, cardiac catheterization continues to be essential for studying cardiac structure and hemodynamics but is associated with some risk. An earlier experience with complications of pediatric cardiac catheterization was reported from this laboratory in 1974 (1). Since that publication, changes in catheterization techniques, equipment, procedures, patient selection and pericatheterization medical management may have affected catheterization-related morbidity and mortality. This study was undertaken to determine the current risks of pediatric cardiac catheterization and to compare them with the results of the 1974 study from this institution. Factors considered significant in effecting changes in specific complications are discussed.

### Methods

**Study patients.** Computerized records of diagnoses, hemodynamic data and complications for all patients undergo-

ing cardiac catheterization in the pediatric laboratory at the University of California, San Francisco were prospectively kept between January 1986 and October 1988. During this period, 1,037 catheterizations were performed in 888 patients and all were included in the study. Formal catheterization reports, inpatient and outpatient records of these patients were examined. The patient age distribution is shown in Figure 1; 59% of the patients were male and 41% female.

**Catheterization technique.** Catheterizations were performed by previously described techniques (2). Patients were usually sedated by administration of a combination of oral diphenhydramine (2 mg/kg body weight; maximal 100 mg) and oral chloral hydrate (75 mg/kg; maximal 2 g). Additionally, oral morphine sulfate (0.1 mg/kg) was given to older patients. Heparin sodium (50 to 100 U/kg per dose as a single bolus injection) was given with dosage based on cardiologist preference. Balloons on flow-directed catheters were inflated with use of carbon dioxide alone. Balloons of dilation catheters were purged with carbon dioxide prior to filling with saline solution.

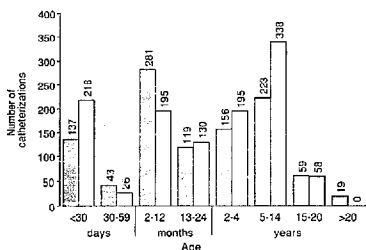
Cineangiography was performed in nearly all patients. Commercially available iodinated contrast materials were used for cineangiograms; ionized contrast medium was used in patients  $>6$  months of age and nonionized contrast medium used in infants  $<6$  months of age and in patients in low output states. Between 0.5 to 2 ml/kg of contrast medium was given for each angiogram, to a maximum of 4 ml/kg per catheterization.

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**Figure 1.** Histogram comparing age distribution of patients undergoing cardiac catheterization in the present study (gray bars) and in the 1974 study of Stanger et al. (white bars) (1). The age scale is expanded at younger ages and compressed at older ages. The age distribution was similar in both studies except that fewer neonates and more infants required catheterization during the present study.

**Interventional procedures** were performed in 152 patients (14.7%) with previously described techniques (3-10).

**Data collection and study design.** A computerized record, made during each catheterization, contained a log of the procedure, hemodynamic measurements, calculations and a record of complications and incidents attributed to the procedure. If a complication occurred, the patient's hospital records were reviewed to evaluate the effect and treatment of the complication. An event was classified as a major complication, a minor complication or an incident. A potentially life-threatening event that required immediate treatment was defined as a major complication; a transient event that had no long-term ill effect on the patient and resolved with specific treatment was defined as a minor complication.

An event that did not affect the patient's condition and required minimal or no treatment was classified as an incident. To facilitate comparison, results are reported in a manner similar to that of previous work from this laboratory (1) with the exception of the separation of minor complications and incidents in the current series.

**Statistics.** Stepwise logistic regression analysis was performed to determine the relation between patient or catheterization variables and the occurrence of complications using a microcomputer and the BMDP Statistical Software package. Variables used in this analysis were age, weight, hemoglobin concentration, arterial oxygen saturation (normal  $\geq 95\%$  vs. abnormal  $< 95\%$ ), heparin dose, contrast agent dose and duration of arterial catheter placement. Complications were examined as a whole and were also grouped into five categories for analysis: death, arrhythmia, vascular, bleeding and miscellaneous. In addition, chi-square analysis with the Yates correction was used to compare the incidence rates of specific complications of patients undergoing interventional/diagnostic versus diagnostic catheterization and in the current versus the 1974 study. A  $p$  value  $\leq 0.05$  was considered significant.

## Results

**General information.** In the study, 1,037 cardiac catheterizations were performed in 888 patients and 152 (14.7%) of these procedures were diagnostic/interventional (Table 1). In 106 procedures there were 15 major complications (1.4%), 70 minor complications (6.8%) and 30 incidents (2.9%) (Table 2). An arterial catheter was placed in 541 (52.1%) of the procedures, in 36 (3.5%) with use of the umbilical artery and in 43 (4.1%) with use of a short 3F femoral artery cannula only. In 45 patients (4.3%) only a femoral or umbilical artery catheter was placed and in 475 patients (45.8%) only a

**Table 1.** Complication Frequency Among 152 Patients Undergoing Interventional Catheterization

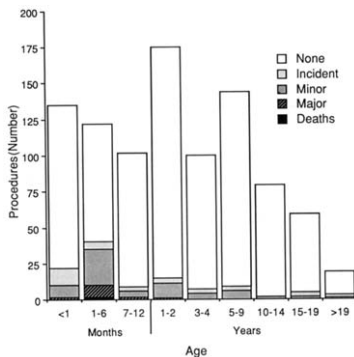
Procedure	Procedures (no.)	Major Complications		Minor Complications		Incidents (no.)
		No.	%	No.	%	
Balloon pulmonary valvuloplasty	53	1	1.8	3	5.7	1
Balloon pulmonary arterioplasty	15	1	6.7	1	6.7	0
Balloon aortic valvuloplasty	17	1	5.9	6	35	0
Balloon atrial septostomy	34	1	2.9	0	0	4
Balloon coarctation dilation	2	0	0	0	0	0
Balloon conduit valve dilation	12	0	0	0	0	0
Transseptal catheterization	4	1	25	0	0	0
Endomyocardial biopsy	8	1*	12.5	3	37.5	1
Blade atrial septostomy	2	0	0	0	0	0
Miscellaneous	5	0	0	1	20	0
Total	152	6	3.9	14	9.2	5
Vascular entry complications only (blood loss, hematoma, pulse loss)	152	2	2*	12	7.9*	0

\*Includes both ventricular fibrillation and death in this patient. †Vascular entry complications accounted for 50% of major complications and 87% of minor complications.

**Table 2.** Complications of 1,037 Diagnostic and Interventional Pediatric Cardiac Catheterizations

	Major		Minor			Incidents	
	Definition	Total No.	No.	Definition	Total No.	No.	Total No.
A. Death		2					
	Contributed to by cath		2				
	Possibly contributed to by cath		0				
	Pericatheterization deaths not attributed to cath		0				
B. Arrhythmia		1*			22		14
	Cardiac standstill		0	Supraventricular tachycardia		9	8
	Ventricular fibrillation;		1*	Atrial flutter		3	0
	ventricular fibrillation not due to cath		11	Sinus bradycardia		0	3
	Prolonged ventricular tachycardia		0	2° AV block		0	3
	Other arrhythmia leading to severe hypotension, discontinuation of the procedure or countershock		0	3° AV block		10	0
C. Hypotension		1			2		1
	Requiring sustained therapy such as pressor agents		1	Transient, responding to volume infusion		2	1
D. Arterial		0			25		0
	Loss of limb		0	Weak or absent pulse after cath requiring thrombolytic therapy		24	0
	Ischemic symptoms		0				
	Requiring surgical exploration of vessel		0	Weak or absent pulse after cath with warm leg, good capillary filling		1	0
E. Perforation of heart or great vessel		2			0		2
	By catheter or guide wire		2	Staining of myocardium by contrast material		0	2
	By contrast material		0				
F. Catheter problems		0			1		4
	Complete breakage of catheter or guide wire		0	Burst balloons without embolism		0	3
	Knotting of catheter		0	Kinking of catheter		0	1
				Failure of dilation balloon to deflate		1	
G. Infections		1			1		0
	Bacterial sepsis (recurrence)		1	Superficial wound infections		1	0
	Local infections requiring surgical drainage		0				
H. Allergic reactions		1			0		5
	Contrast		1	Contrast		0	5
	P. medication, anesthetic or drugs		0	Premedication, anesthetic or drugs		0	0
	Transfusion reactions		0	Transfusion reactions		0	0
	Pyrogen reactions; temperature 104°		0	Temperature 103° to 103.8°		0	0
I. Embolism		1*			1		0
	(See A above)		1*	Embolization of balloon occlusion device		1	0
J. Cardiac		2			2		0
	Severe hypoxemic spells		2	Mild or moderate hypoxemic episodes		2	0
	Acute pulmonary edema		0				
	Myocardial infarction		0				
K. Bleeding		5			13		1
	Requiring surgical intervention†		0	Local hematomas		11	
	Requiring transfusion		5	Appreciable but not requiring transfusion		2	1
L. Pneumothorax		0			0		1
	Contributed to by the cath		0	Not contributed to by the cath		0	1
M. Other		1			3		2
	Seizure		1	Miscellaneous		3	2
Total		15			70		30
Residual		4			6		0
	Mild aortic insufficiency		1	Persistent pulse loss		5	
	Potential for sequelae		3	Conversion of 2° to 3° AV block		1	

Data shown are numbers of complications. Multiple complications occurred in some procedures. \*Each includes one patient that died in association with catheterization; these are therefore not counted twice in Total. †Excluding cardiac perforations. AV = atrioventricular; cath = cardiac catheterizations; 2° = second degree; 3° = third degree.



**Figure 2.** Histogram showing age distribution of patients with and without complications. The complication severity is indicated by the shading. The age scale is expanded at the younger ages and compressed at older ages.

venous catheter was placed. Vascular entry was by percutaneous technique in all patients but four (0.4%) who required surgical cutdown. Data on catheterization site and duration were missing in 21 patients. When an arterial catheter was placed, 448 patients (83%) received heparin sodium at a mean dose of  $66 \pm 32$  U/kg. When a venous catheter alone was placed, 269 (56%) received heparin sodium at a mean dose of  $70 \pm 24$  U/kg.

The major and minor complications and incidents are listed in Table 2. The number of complications and incidents by patient age are shown in Figure 2.

**Deaths.** Two deaths (0.19%) were directly attributed to complications of the catheterization procedure. The first catheterization-related death occurred in a 6-month old infant with a single ventricle and a patent ductus arteriosus. A balloon-tipped angiographic catheter that had previously been used to occlude a patent ductus arteriosus was passed retrogradely through the aortic valve into the ventricle. The balloon then failed to reflate when 1.5 ml of carbon dioxide was introduced<sup>4</sup>. Shortly thereafter the patient had a seizure, developed cardiopulmonary arrest and could not be resuscitated. Necropsy revealed no evidence of cardiac injury from the catheter and no evidence of gas embolism in the cerebral or coronary arteries.

The second catheterization-related death occurred in a 6-month old infant with intractable junctional ectopic tachycardia and cardiomyopathy. Catheterization was performed for electrophysiologic study and endomyocardial biopsy. After four biopsy specimens of the right ventricular septum were obtained, he developed ventricular fibrillation that was refractory to defibrillation and prolonged cardiopulmonary

resuscitation. Hemopericardium was excluded by pericardiocentesis and then open pericardiectomy.

Two postcatheterization deaths in newborns were thought to be caused by the underlying congenital heart disease. One infant had severe Ebstein anomaly with marked cyanosis and a large patent ductus arteriosus with intractable congestive failure during treatment with prostaglandin E<sub>1</sub>. During the procedure, the catheter was thought to have perforated the atrialized right ventricle. The catheter was left in place and the patient was taken to the operating room for catheter removal, ductus ligation and an aortopulmonary shunt. At operation, neither hemopericardium nor perforation was found and the catheter was removed without incident. After ligation of the large patent ductus arteriosus he became markedly hypoxic and died in the operating room before a shunt could be placed. Necropsy showed no evidence of perforation. The other postcatheterization death was in a critically ill 1-day old infant with severe aortic stenosis and endocardial fibroelastosis who presented with acidosis and hypotension. Despite treatment with assisted ventilation, prostaglandin E<sub>1</sub>, bicarbonate and inotropic support before and during catheterization, low cardiac output persisted and she died in the intensive care nursery 4 h later.

**Arrhythmias.** Ventricular fibrillation occurred in two patients (0.19%), both of whom had a severe cardiomyopathy. The first patient was described in the preceding section on Deaths. The other, a patient with arrhythmogenic right ventricular dysplasia and a large patent ductus arteriosus, had ventricular fibrillation after removal of the catheters that responded readily to defibrillation; additionally, ventricular tachycardia occurred after ductus ligation. In view of the diagnosis and circumstances, the postcatheterization episode of fibrillation was not attributed to catheterization. There were no episodes of sustained ventricular tachycardia. No attempt was made to keep records of isolated or short nonsustained runs of ventricular ectopic beats.

**Atrial.** Atrial arrhythmias were reported in 23 patients (2.2%). Seventeen patients had supraventricular tachycardia; eight of these tachycardias, classified as minor complications, were treated with catheter-induced premature ventricular beats or by administration of verapamil or propranolol; eight tachycardias, classified as incidents, resolved spontaneously. Three patients had atrial flutter (classified as a minor complication) that was converted to sinus rhythm by atrial overdrive pacing. Three patients had sinus bradycardia (incident).

**Atrioventricular (AV) block.** Third-degree AV block was reported in 10 patients (1%) and was classified as a minor complication. Of the 10 episodes, 6 were in patients with AV discordance. Nine resolved; six with atropine, one spontaneously in several days and two with temporary transvenous pacing. One patient with single ventricle, transposition, subpulmonary stenosis and prior second-degree AV block developed persistent, asymptomatic third-degree AV block with a satisfactory junctional escape rate. Brief, self-limited

second-degree block was reported in three cases (0.3%) and was classified as an incident.

**Hypotension.** Four patients (0.4%) developed hypotension during catheterization. One (major complication) required dopamine infusion, two (minor complications) responded to volume infusion and one (incident) had brief hypotension that resolved spontaneously.

**Arterial complications.** Twenty-five arterial complications (2.4%) were noted and all were classified as minor. All 25 patients had decreased pulse or perfusion in the limb in which an arterial catheter had been placed. One patient improved without therapy. Intravenous urokinase (2,000 U/kg bolus, then 2,000 to 4,000 U/kg per h infusion) was given to 24 patients with improvement of perfusion or return of pulse in 16. Of eight patients with a diminished pulse after administration of urokinase, the pulse subsequently returned to normal in three and was still diminished but with good perfusion in five. Three of the latter patients had undergone balloon aortic valvuloplasty.

**Perforation of the heart or great vessel.** There were two cardiac perforations (0.2%); one involved a transseptal sheath and the other a guide wire. The first occurred in a 2-month old infant with a ventricular septal defect, mitral stenosis and subaortic stenosis. He underwent retrograde arterial catheterization and atrial transseptal catheterization. When the transseptal sheath was removed at the end of the procedure, he immediately became hypotensive and was treated with volume infusion, pericardiocentesis, endotracheal intubation and mechanical ventilation. After surgical drainage of the pericardium by a mediastinal tube, the bleeding stopped and his condition became stable. A small hole with a burr was noted near the distal end of the Teflon transseptal sheath. This burr apparently tore the inferior vena cava-right atrial junction, which was later repaired at operation. The second perforation, an aortic cusp perforation by a guide wire, occurred in a 2-month old infant who became transiently hypotensive during an attempt to pass a catheter through the aortic valve by using a guide wire. He was found to have new mild aortic regurgitation that required no treatment.

A third perforation was suspected but proved not to be a perforation (see discussion of the infant with Ebstein anomaly under Deaths). Two small contrast stains of the myocardium without associated electrocardiographic changes were reported as incidents.

**Catheter problems.** Five isolated catheter problems, including one minor complication (0.1%) and four incidents (0.4%), were reported. The minor complication had the potential for causing a major complication. During balloon aortic valvuloplasty in a 2-month old infant, balloon deflation was very slow and difficult. The balloon was withdrawn to the ascending aorta, and deflation was eventually achieved. There was bradycardia while the inflated balloon obstructed the aortic valve but no sequelae. Incidental balloon rupture was reported in three patients, once in a dilation catheter and twice in a right-sided angiographic catheter. The fourth

incident was kinking of a 4F pigtail catheter during retrograde arterial catheterization in a 2-month old infant.

**Infections.** Two patients (0.19%) had infections, one a major and the other a minor complication. The major complication was a recurrent infection in a 2-year old boy with tetralogy of Fallot and hypoplastic pulmonary arteries who previously had *Staphylococcus aureus* mediastinitis after surgical relief of right ventricular outflow tract obstruction. A year later, he underwent cardiac catheterization and balloon pulmonary arterioplasty. Two days after the procedure, sepsis developed with the same strain of *Staphylococcus aureus* that had caused his previous mediastinitis. As a precaution, he was treated with long-term intravenous antimicrobial therapy as though he had bacterial endocarditis. The other reported infection was a minor wound infection that was treated with topical and oral antibiotic agents.

**Allergic reactions.** Six allergic reactions to contrast medium occurred. One was anaphylaxis, a major complication; the other five were incidents consisting of transient rash after angiography.

**Embolism.** In addition to the probable gas embolism discussed previously under Deaths, there was one minor embolism. During an attempt to occlude a Blalock-Taussig shunt in a 17-year old youth, a detachable balloon device embolized to a distal branch of the right pulmonary artery. The patient had no symptoms, radiologic changes or sequelae.

**Cardiac complications.** Hypercyanotic episodes occurred in 4 of 33 infants with unoperated tetralogy of Fallot (12%) within 24 h of catheterization; the episode was considered a major complication in 2. One of these two episodes occurred in a 3-month old infant who developed severe cyanosis and acidosis 12 h after catheterization and was treated with endotracheal intubation, ventilation and volume infusion. The second occurred in a 5-month old infant who had 10 min of severe cyanosis in the catheterization laboratory and was treated with oxygen, morphine sulfate, red cell transfusion and volume infusion. Two minor episodes occurred during catheterization in infants who responded to treatment with oxygen, morphine sulfate and volume infusion.

**Bleeding.** Bleeding complications and incidents were reported in 19 patients (1.8%). Eleven had "moderate to large wound hematomas" classified as minor complications. Various degrees of blood loss occurred in the other eight patients, including five who required transfusion and were considered to have a major complication, two with significant blood loss that did not require transfusion (minor complications) and one with mild rectal bleeding 6 h after catheterization (incident). Four of the patients with blood loss and three with hematomas had undergone interventional catheterization performed with large profile catheters and multiple catheter exchanges.

**Pneumothorax.** A 1-day old infant with obstructed total anomalous pulmonary venous connection was being ventilated with high pressures when a prior pneumothorax re-

**Table 3.** Patient and Catheterization Variables Related to Complications: Results of Stepwise Logistic Regression Analysis

Group	Procedures (no.)	Patient Age (mo)	Patient Weight (kg)	Hemoglobin Concentration (g/100 ml)	Percent Arterial Saturation	Heparin Dose (U/kg)	Contrast Dose (ml/kg)	Duration of Arterial Catheter Placement (min)
No complication	896	51 (66)	16 (17)	13.4 (2.4)	91 (9)	45 (37)	3.0 (1.2)	36 (51)
All complications and incidents	102	36 (63)	12* (16)	13.3 (2.7)	90 (10)	49 (54)	2.9 (1.3)	56* (62)
Vascular	22	11* (11)	7 (3)	12.4 (2.0)	91 (12)	59 (35)	2.9 (1.4)	78* (55)
Bleeding	16	57 (74)	17 (20)	12.7 (2.0)	94 (5)	51 (42)	3.1 (1.4)	91* (88)
Arrhythmia	36	44* (72)	13* (15)	14.0 (3.0)	89 (10)	51 (75)	3.2 (2.6)	36 (47)
Death	2	3 (4)	5.1 (2.2)	14.6 (6.4)	70 (38)	40 (57)	2.1 (0.9)	84 (54)
Miscellaneous	26	34 (66)	13 (20)	13.5 (2.8)	91 (8)	39 (49)	2.6 (1.2)	43 (55)

Values are mean values  $\pm$  SD. \* $p < 0.05$  versus patients with no complications.

curring and a chest tube was placed. This event was classified as an incident because it was not catheterization related.

**Other complications.** Six miscellaneous events (0.6%) reported included one major complication, four minor complications and one incident. The major complication was a 30-s seizure that occurred in a 3-month old patient after a partially inflated balloon catheter in the ascending aorta probably obstructed a carotid artery. Minor complications included two postcatheterization iliofemoral venous occlusions with edema of the involved limb and normal pulses. Each patient responded to treatment with heparin. A post-catheterization minor complication occurred in a 16-month old infant who fell from the catheterization table while partially restrained, struck his forehead on the base of the table and developed a small (2-cm) subcutaneous hematoma. A 6-day old infant was found on aortography to have a small intimal flap in the right carotid artery after catheter manipulation of a floppy-tipped guide wire in the aortic arch. A 16-year old patient with recurrent coarctation of the aorta had chest pain (incident) while the catheter was being manipulated in the descending aorta. None of the miscellaneous complications or incidents were associated with sequelae.

**Association of patient or catheterization variables and complications.** Several patient or catheterization variables were associated with complications (Table 3). Smaller patients and those who had a longer duration of arterial catheter placement were more likely to have vascular complications, although this association was weak ( $p \leq 0.05$ ). Smaller, younger patients were slightly more likely to have arrhythmias ( $p \leq 0.05$ ). Patients who had a longer duration of arterial catheter placement were also more likely to have bleeding complications ( $p \leq 0.05$ ). Heparin dose was not related to the occurrence of vascular or bleeding complications ( $p > 0.05$ ). Hemoglobin concentration, arterial saturation, dose of contrast medium and duration of venous

catheter placement were not significantly related to complications.

**Interventional catheterization.** Six major complications (3.9%), 14 minor complications (9.2%) and 6 incidents (3.9%) occurred in 152 interventional procedures (Table 1). Of these 26 events, 5 were due to and 15 were probably contributed to by the interventional procedure. The combination of all complications and incidents tended to be more frequent for interventional than for diagnostic catheterizations but the difference was not statistically significant ( $p > 0.05$ ). Major complications were more than three times as frequent in diagnostic/interventional as in diagnostic procedures (3.9% vs. 1%,  $p < 0.01$ ); most of the difference was due to vascular access complications, which were more than three times as frequent for interventional as for diagnostic catheterizations (10.5% versus 3.2%;  $p < 0.005$ ). Furthermore, among patients undergoing interventional procedures, vascular entry complications accounted for 50% of the major and 86% of the minor complications.

The frequency of complications and incidents appeared to be particularly high among patients who had endomyocardial biopsy (Table 1); however, there were too few patients to test statistical significance. This group included the patient who died of ventricular fibrillation and three patients who had minor complications of arterial entry for retrograde left ventricular biopsy (two pulse losses that responded to atropine and one hematoma).

**Residua and sequelae.** The majority of the catheterization complications were successfully treated or were self-limited and the patients were without residua. Although an accurate assessment of the residua and sequelae of complications is not possible, reasonable estimates of evident residua and potential for sequelae can be made. Of the 13 patients with nonfatal major complications, 1 infant had evident residua, that is, mild aortic insufficiency. An additional two infants with severe hypoxemic episodes and one with a brief seizure

had no neurologic abnormality indicating residua; however, subtle residua or sequelae cannot be excluded. Of 70 minor complications there were 6 evident residua: 1 conversion of second-degree to third-degree AV block and 5 persistent pulse losses including 3 in patients who had undergone balloon aortic valvuloplasty. The overall incidence of evident residua was 0.7% and that of potential sequelae, 0.3%.

## Discussion

**Comparison with previous studies.** A previous study of major and minor complications of pediatric cardiac catheterizations performed at this institution (1) in 1974 documented the decrease in mortality and morbidity that had occurred since the 1968 Cooperative Study on Cardiac Catheterization (11). Since the 1974 study, there have been many changes in catheterization techniques, equipment, contrast medium, patient selection, pericatheterization management and the conduct of pediatric cardiac catheterizations. The impact of these changes is reflected in changes in the incidence of catheterization complications. A comparison of the diagnostic and balloon atrial septostomy cases in the present series with similar cases in the previous study shows a decrease in the incidence of major complications (from 2.9% to 1%;  $p < 0.0001$ ), minor complications and incidents (from 11.7% to 7.9%;  $p < 0.006$ ) and pericatheterization deaths not attributable to catheterization (from 2.8% to 0.2%;  $p < 0.0001$ ). The largest changes in specific complications were a decline in frequency of arrhythmias and a reduction in the number and severity of arterial complications. These reductions in mortality and morbidity probably were due to a variety of factors that will be considered separately.

**Decrease in pericatheterization deaths.** The marked decrease in pericatheterization deaths is attributable primarily to the use of prostaglandin E<sub>1</sub>. Its ability to maintain ductal patency and thereby improve hemodynamics in neonates with severe hypoxemia or severe left-sided obstructive lesions has resulted in precatheterization stabilization of critically ill neonates as well as a dramatic reduction in postcatheterization deaths due to clinical deterioration caused by the patient's underlying cardiac condition. In the present study there were only two such deaths. In contrast, in the 1974 study (1) there were 34 such deaths among 218 neonates and an analysis showed a very clear relation of pericatheterization deaths to the severity of illness before catheterization. No such analysis was undertaken in the current study because the number of postcatheterization deaths was too small. The role of markedly improved Doppler echocardiographic technology in reducing the number of postcatheterization deaths is not clear. It has allowed the avoidance of many catheterizations in neonates with cardiac abnormalities of varying severity. Whether it has selected out cases with more lethal lesions is not known.

**Decrease in major arterial complications.** Major arterial complications in the two studies from this laboratory differed markedly as did the techniques of arterial entry. In the

earlier study, most patients underwent an arterial cutdown procedure, whereas percutaneous techniques have been used almost exclusively since then. In the previous study, six patients with an arterial cutdown underwent postcatheterization surgical exploration of the artery and the event was classified as a major complication. An additional 27 patients underwent reopening of the vessel by the cardiologist or were discharged with diminished pulse but good perfusion; these patients were classified as having a minor complication. In the current study, there were no major and 25 minor arterial complications. One of the 25 minor complications improved spontaneously; of the remaining 24, 16 improved with urokinase and 3 with subsequent spontaneous resolution. It is possible that in some of the patients who received urokinase the complication might have resolved without treatment; consequently, the apparent efficacy of thrombolytic therapy may be slightly exaggerated.

The current study clearly demonstrates that for diagnostic procedures, the combined use of percutaneous technique, heparinization and, when necessary, thrombolytic therapy has eliminated major arterial complications requiring surgical intervention. Although the number of minor arterial complications in the two studies was the same, fewer patients in the current study were discharged with a diminished pulse. Recently, activated clotting times have been monitored during catheterization to help regulate heparin dosage. It is hoped that this procedure will decrease the number of patients requiring thrombolytic therapy.

**Decrease in arrhythmias.** The third area of considerable improvement was arrhythmias; the number of both major and minor arrhythmias was dramatically reduced. Undoubtedly, this is the result of improved catheterization equipment including the expanded use of flow-directed balloon-tipped catheters and pigtail catheters that minimize myocardial stimulation as well as tip-deflecting and other guide wires that facilitate catheter manipulation. Additionally, it is likely that the incidence of arrhythmias has been reduced indirectly by the relative safety of percutaneous arterial entry; that is, the more liberal use of retrograde left heart catheterization has decreased the need for manipulating venous catheters through septal communications to the left side of the heart. Although the number of arrhythmias decreased in all age groups, infants continued to have the highest incidence. Levotransposition of the great arteries was associated with an increased incidence of AV block.

**Hypercyanotic spells.** Most other complications occurred at similar frequencies in both studies. A notable exception was hypercyanotic spells in unoperated tetralogy of Fallot, which were more frequent in the current study (12%) than in the previous study (3.6%), although the difference was not statistically significant ( $p > 0.25$ ). In addition, there were differences in patient population. In the earlier study catheterization was performed in all patients with unoperated tetralogy of Fallot, whereas in recent years it has been performed only in selected patients, such as those with questionable pulmonary arteries. Hypercyanotic spells oc-

curred despite appropriate sedation, intravenous fluids to prevent hypovolemia, use of nonionic contrast medium and attention to hemoglobin concentration, and they occurred not only during the procedure but as late as 12 h afterward. Despite the precautions taken, patients with unoperated tetralogy of Fallot who require catheterization are at risk for hypercyanotic spells; the availability of therapeutic measures during and after the procedure is essential. Other than levo-transposition and diagnoses associated with interventional procedures, tetralogy of Fallot was the only cardiac abnormality associated with an increased complication rate.

**Role of patient age.** A number of complications were age related (Fig. 2). Both deaths resulting from catheterization occurred in infants and both postcatheterization deaths due to the cardiac abnormality occurred in unstable newborns. Major complications in general and specific minor complications such as vascular and arrhythmias occurred more frequently in infants, a finding similar to that reported in other studies (1,12,13). Similarly, the risk of cardiac perforation is greatest in newborns and infants because of the relatively thin cardiac structures. The use of softer balloon-tipped flow-directed catheters has minimized this risk by distributing the contact of the catheter over a wider area. It is noteworthy that neither perforation in this study was caused by a catheter; one was caused by a guide wire and the other by a transseptal sheath burr.

**Changes in patient management and procedures since the previous study (1).** Additional changes in patient management have evolved even since the later study period. Two patients who died would be managed differently at this time. The infant with cardiomyopathy and refractory incessant supraventricular tachycardia would undergo radiofrequency AV node modification or, if necessary, AV node ablation with placement of a pacemaker. The markedly hypoxic newborn infant with severe Ebstein anomaly who also had severe pulmonary edema during treatment with prostaglandin E<sub>1</sub> might undergo palliative treatment with surgical closure of the tricuspid valve and a restrictive aortopulmonary shunt.

The patients in the current and the previous study (1) differed in at least three ways. First, patient selection for catheterization has changed in the past 15 years. Doppler echocardiography and, more recently, the addition of color flow mapping have provided sufficient diagnostic information to allow many patients with simple lesions and some with straightforward complex abnormalities to undergo cardiac surgery without catheterization, thereby removing many low risk children and a few high risk neonates from the recent catheterization population. Second, the current study includes interventional procedures that were not performed in 1974. Third, there has been an increase in the number of technically difficult diagnostic studies such as catheterization of patients with complex anatomy to assess the advisability of a Fontan procedure. Although the net effect of each of these differences is an increase in the overall complexity of the procedures performed in the later study, complication

rates have decreased, suggesting a degree of improvement beyond that indicated by the statistics.

**Interventional catheterization has introduced a small number of new complications.** Although it did not carry a higher overall complication risk than that of routine diagnostic catheterization, there was nearly a threefold higher incidence of vascular access complications including pulse loss, blood loss and hematoma. Other studies (14-20) have reported similar complication rates for interventional catheterization and have stressed that pulse loss was particularly common in infants <6 months of age who underwent retrograde arterial interventional procedures (17,20). The long-term implications of these arterial complications in young infants undergoing balloon aortic valvuloplasty are not known. Longer clinical follow-up will be required to examine these sequelae and weigh their risk against that of surgery. It is likely that the recently available low profile dilation catheters (21) that can be passed through sheaths will reduce the incidence of arterial complications, hematomas and blood loss associated with retrograde arterial interventional procedures.

**Conclusions.** The incidence of major complications and pericatheterization deaths associated with pediatric cardiac catheterization has decreased markedly since the 1974 study (1) despite an increase in the complexity of the diagnostic studies and the advent of interventional procedures. Additionally, 89% of complications were successfully treated or were self-limited; consequently, the incidence of residua was very low (0.9%). The risks of pediatric cardiac catheterization continue to decline. It remains a reasonably safe method for augmenting, when necessary, information provided by noninvasive diagnostic techniques and for therapeutic interventions.

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